

FORM PTO-1390
(REV 5-93)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

Mewburn

U.S. APPLICATION NO. 09/463098
not yet assignedINTERNATIONAL APPLICATION NO.
PCT/EP99/03344INTERNATIONAL FILING DATE
14 May 1999PRIORITY DATE CLAIMED
19 May 1998

TITLE OF INVENTION

MIMOTOPES OF HYPERVARIABLE REGION 1 OF THE E2 GLYCOPROTEIN OF HCV AND USES THEREOF

APPLICANT(S) FOR DO/EO/US

Alfredo NICOSIA; Armin LAHM; Anna TRAMONTANO; Riccardo CORTESE

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
 2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
 3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
 4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
 5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
 6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
 - ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
 - ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
 - ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11. to 16. below concern other document(s) or information included:
11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
 13. ☒ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
 14. ☐ A substitute specification.
 15. ☐ A change of power of attorney and/or address letter.
 16. ☒ Other items or information:
Copy of Form PCT/IB/308

09/463098

430 Rec'd PTO 1-8 JAN 2000

APPLICATION NO. (37 CFR 1.52)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
not yet assigned		PCT/EP99/03344		Mewburn	
17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
Basic National Fee (37 CFR 1.492(a)(1)-(5)):					
Search Report has been prepared by the EPO or JPO..... 840.00					
International preliminary examination fee paid to USPTO (37 CFR 1.482)					
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))..					
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....					
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 840.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 130.00	
Claims	Number Filed	Number Extra	Rate		
Total Claims	87 -20 -	67	X 18.00	\$ 1,206.00	
Independent Claims	2 -3 -	0	X 78.00	\$ 0	
Multiple dependent claims(s) (if applicable)				+	
TOTAL OF ABOVE CALCULATIONS =				\$ 2,176.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				\$	
SUBTOTAL =				\$ 2,176.00	
Processing fee of \$130.00 for furnishing the English translation later the <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	
TOTAL NATIONAL FEE =				\$ 2,176.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ 0	
TOTAL FEES ENCLOSED =				\$ 2,176.00	
				Amount to be:	
				refunded \$	
				charged \$	

- a. ☒ A check in the amount of \$ 2,176.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-1406 A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Kathleen D. Rigaut, Ph.D., J.D.
DANN, DORFMAN, HERRELL AND SKILLMAN
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43,047

REGISTRATION NUMBER

PCT/EP99/03344 18 JAN 2000

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PCT/EP99/03344

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URGENT

International Searching Authority
European Patent Office
PO Box 5818 - Patentlaan 2
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THE NETHERLANDS

13 August 1999

URGENT REQUEST FOR RECTIFICATION

Dear Sirs

International Patent Application No PCT/EP99/03344
Applicant: Istituto Di Ricerche Di Biologia Molecolare P. Angeletti S.p.A.
Our Ref: SMW/FP5769302

I write to request the rectification of an error in this patent application under Rule 91 of the PCT. Enclosed are

- (I) a replacement page 80 of the description, in triplicate;
- (II) hand-amended description page 80, showing the error and correction;
- (III) Nishihara, *et al*, (1993), *Gene*, 129: 207-214.

The error is in the nucleotide sequence of "oligo rev" (page 80, line 11). The originally filed application shows an "L" three bases from the end. This should be a T.

The error is obvious. No nucleotide "L" exists.

Rectification of "L" to "T" is also obvious based on the content of the specification. Anyone would immediately realise that nothing else could have been intended.

Page 80 states that "Oligo rev" is used as a reverse primer to clone the $\Delta E2$ gene using the vector described in Nishihara *et al* as PCR template (see page 80, line 5 to 11 of the present application). This vector is shown in Figure I(B) on page 210 of Nishihara, *et al*.

The $\Delta E2$ gene codes amino acids 411 to 683 of the HCV polyprotein (Page 79, lines 4 to 9; Page 80, lines 5 to 6 of the application).

Figure 1B of Nishihara shows an antisense primer (primer 31) which anneals to the vector, so as to produce a PCR product which encodes a peptide terminating at amino acid 683. As mentioned above, the Applicant's PCR product ($\Delta E2$) encodes a peptide which terminates at amino acid 683. Therefore, the present Applicant's primer "oligo rev" and primer 31 necessarily anneal to the same part of the vector.

The sequence of primer 31 is shown on page 211 of Nishihara (enclosed). For comparison, "oligo rev" and primer 31 are aligned below:

Nucleotides shown in upper case anneal to the vector. Nucleotides shown in lower case do not anneal to the vector, but are extra sequences such as restriction sites and His tag encoding (as explained on page 80 of the specification and in Figure 1B of Nishihara, *et al*) and can be disregarded for present purposes. Comparison of the sequences which anneal to the vector clearly shows that the annealing sequence should be CGG TAG.

Primer 31 (5' to 3')

tga gaa ttc tta gtg gtg gtg gtg gtg gtg CGG TAG GGT GGT GAA

Oligo rev (5' to 3')

tcc gga tcc tta gtg gtg gtg gtg gtg gtg CGG LAG

Summarising

It is obvious that there is an error in the sequence of oligo rev on page 80, and obvious that the error is the reference to a nucleotide as "L", there being no such nucleotide.

Furthermore, it is obvious that the rectification offered, namely the nucleotide "T", is the only one that could have been intended.

A time limit has not yet been set for the submission of the sequence listing for this application, but request that the rectification is considered as soon as possible to allow submission of a single, correct sequence listing at the appropriate time.

Yours faithfully

H Alan Gura
for Seán M Walton
APPOINTED AGENT

Encs: Replacement page 80 of the description, in triplicate
Hand-amended description page 80
Nishihara, *et al*, (1993), *Gene*, 129: 207-214.

KMT/kmt/AG

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BOX PCT

Date of Mailing January 18, 2000	
Applicant's or Agent's Reference Mewburn Nicosia	
IDENTIFICATION OF THE INTERNATIONAL APPLICATION	
Int'l. Appln. No. PCT EP99/03344	Int'l. Filing Date 14 May 1999
Applicant (name) ISTITUTO DI RICERCHE DI BIOLOGIA MOLECOLARE P. ANGELETTI S.P.A.	
TRANSMITTAL OF LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)	

CERTIFICATE OF MAILING
BY EXPRESS MAIL UNDER 37 CFR §1.10

NUMBER OF EXPRESS MAIL MAILING LABEL EL182475635US
DATE OF DEPOSIT WITH POSTAL SERVICE January 18, 2000

I hereby certify that this paper or fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. §1.10 on the date indicated above, and is addressed to the COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, D.C. 20231.

Jane C. Bozan
Typed Name of Person
Mailing Paper or Fee

Jane C. Bozan
Signature of Person Mailing
Paper or Fee

PTO/PCT Recd 25/10 JAN 2000

PCT/EP99/03344

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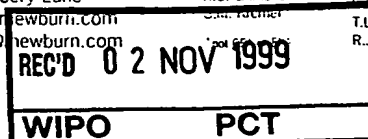
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S.J. "Gid"	M.J. Sanderson
A.H. Brasnett	I.A. Stuart
R.S. Grimshaw	T. Taylor
	T.L. Watkin
	R.J. Watson

URGENT

World Intellectual Property Organisation
34, Chemin des Colombettes
1211 Geneva 20
SWITZERLAND

29 October 1999



BY FACSIMILE

CONFIRMATION

Dear Sirs

International Patent Application No PCT/EP99/03344

Applicant: Istituto Di Ricerche Di Biologia Molecolare P. Angeletti S.p.A.

Our Ref: SMW/FP5769302

In accordance with Rule 91.1(f), I request publication of a request for rectification of an error which has been refused by the EPO as International Searching Authority. In this respect, please debit the requisite official fees of CHF 86.00 from out deposit account number 23187 under reference number WF0069.

I enclose a copy of the request for rectification (including a hand-amended copy of page 80), and a clean copy of the rectified page 80.

Yours faithfully

Simon M Kremer
for Seán M Walton
APPOINTED AGENT

Encs: Copy of Request for Rectification
Hand-amended page 80
Replacement page 80

SMW/smw/AG